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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,000	11/14/2003	Vanessa Chisholm	P1746R1P1	1570
9157	7590	02/05/2008		
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER GUZO, DAVID	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 02/05/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/714,000

Applicant(s)

CHISHOLM ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 59-61, 63-102 and 104-116 is/are pending in the application.
- 4a) Of the above claim(s) 91, 92, 100, 101, 112 and 114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-61, 63-90, 93-99, 102, 104-111, 113, 115 and 116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/07 has been entered.

### **Election/Restriction**

Claims 91-92, 100-101, 112 and 114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/29/05.

### **Obviousness Type Double Patenting Rejections**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59-61, 63-90, 93-99, 102, 104-111, 113 and 115-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46, 49-90, 93-99 and 101-104 of copending Application No. 11/535,003 (hereafter the '003 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a polynucleotide comprising, in operable linkage: (a) a fusion gene comprising a first selectable gene and an amplifiable second selectable gene; (b) a selected sequence encoding a desired product; and (c) a promoter, wherein the first selectable gene is not an amplifiable selectable gene (see especially claim 62 of the '003 application) as well as host cells comprising said polynucleotides and kits comprising said polynucleotides. All of the instant claims recite that the polynucleotide comprises a fusion gene between a first selectable gene and an amplifiable second selectable gene wherein the first selectable gene is not an amplifiable selectable gene as well as a sequence encoding a desired product and a promoter. The claims of the '003 application recite the same components as instantly claimed (see claim 1 of the '003 application). Claim 8 of the '003 application recites a fusion gene between the first and

second markers and Claim 62 of the co-pending application recites that the first selectable gene is not amplifiable. All other limitations of the instant claims are likewise recited in the '003 claims. The instant claims are therefore obvious over the claims in the '003 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have responded to this provisional Obviousness Type Double Patenting rejection by requesting that the provisional rejection be held in abeyance until allowable subject matter is indicated.

In response, the examiner notes that the rejection will be maintained.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61, 63-90, 93-99, 102, 104-111, 113 and 115-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record in the previous Office Actions (mailed 6/5/07, 8/24/07) and for reasons outlined below.

Applicants assert that "amplifiable selectable gene" and "selectable gene that is not amplifiable" have different meanings and refer to portions of the instant specification

to support said assertion. Applicants assert that the specification clearly indicates that "amplifiable selectable genes" are a subset of "selectable genes" and that the phrase "amplifiable selectable gene" does not encompass all selectable genes.

This is not found persuasive because the portion of the specification referred to by applicants merely indicates that not all selectable markers are amplifiable without providing any reasoning or data to support this assertion, and without providing any indication of how a selectable marker which is **not amplifiable** differs structurally from a marker that is **amplifiable**.

With regard to whether the neomycin resistance gene is amplifiable, applicants assert that Thilly does not provide support for the statement in USP 5,919,635 that neomycin resistance marker is amplifiable and applicants cite Kaufman to indicate that neomycin resistance marker is not amplifiable.

This argument is not found persuasive because Thilly is not cited in 5,919,635 as support for the fact that the neomycin resistance marker is or is not amplifiable, only that selectable markers are reviewed in Thilly. With regard to applicants' citation of Kaufman, Kaufman merely indicates that neomycin resistance gene has not been demonstrated to be amplifiable, not that it is not amplifiable. Indeed, the art is replete with references indicating that neomycin resistance gene is amplifiable (for example, see USP 6,677,134, columns 23, 29-30, etc. which teaches that plasmids comprising the neomycin resistance gene can be amplified wherein the resistance marker can be amplified to 20-50 copies per cell).

Applicants also assert that the instant specification restricts amplifiable selectable genes to genes which are capable of being selected and amplified using a corresponding amplifying agent. This argument is not persuasive because the specification does not limit amplifiable selectable genes to those which are amplified using a corresponding amplifying agent. Finally, applicants' arguments that the examiner's definition of an "amplifiable selectable gene" (as determined from the instant specification) are not supported by the specification and are not persuasive. The examiner was indicating that given the definition of "amplifiable selectable gene" in the instant specification (see p. 12), it would appear that any given selectable marker gene can be amplified.

For reasons outlined above, the rejection stands.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
January 25, 2008

  
DAVID GUZO  
PRIMARY EXAMINER